

April 16, 2010

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Dear Dr. White:

We appreciate the opportunity to comment on the most recent draft of the NTP Brief on Soy Infant Formula dated March 16, 2010. We recognize and acknowledge the efforts and level of expertise of the expert panel; however, there are several areas of concern that we deem important to highlight.

The brief appears to have gone beyond the scope of that originally proposed in the Federal Register Notice (Volume 73, no 192) dated October 2, 2008. The action was to have an "evaluation of the scientific evidence regarding the potential reproductive and/or developmental toxicity associated with genistein and soy formula" by an expert panel. The panel clearly included not only soy infant formula and genistein, but also the individual isoflavones in this review.

In addition, on page 9 (Figure 2) toxicity endpoints in humans were expanded to include: "bone mineral density, allergy/immunology, thyroid function, cholesterol, diabetes mellitus, and cognitive function" which clearly goes beyond reproductive and/or developmental toxicity assessment. Also on page 9 (Figure 3) the terms "soy diet", "soy protein isolate", "mixtures of soy isoflavones, daidzein, glycitein, or equol" are shown in addition to soy infant formula and genistein. The relevance of studies investigating these other soy-containing products and isolated isoflavones and/or metabolites to assessing the potential reproductive and/or developmental toxicity of soy infant formula and genistein alone has not been established. We are also concerned about the significant weight the panel placed on rodent studies in which soy products or isoflavones were given to animals because these products are not equivalent to soy infant formula.

Another matter of concern is the answer of "possibly" to the section headings on pages 7 and 33 "Can soy infant formula or its isoflavone contents adversely affect human development?" and "Should feeding infants soy infant formula cause concern?". We strongly request that "possibly" be changed to "probably not" to be more in line with the panel's overall conclusion that there is "minimal concern" about the safety of soy infant formula.

In conclusion, soy infant formula remains a healthful and important option for mothers who, for a variety of reasons, cannot or choose not to breast feed or use cow's milk formula. We encourage the Expert Panel to exercise caution when communicating their NTP Brief summary

report to make it clear what “minimal” level of concern actually means in practice to parents and pediatricians choosing soy infant formula. It is important not to alarm parents who have chosen soy infant formula or to unjustifiably dissuade parents from doing so in the future.

Again, we appreciate this opportunity to submit public comments regarding the expert panel’s brief of the soy infant formula report.

Sincerely,

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